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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/935,629 09/23/97 BATES

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EXAMINER

IM52/0613

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PITTSBURGH PA 15209

ALEXANDER, L

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

06/13/01

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.		Applicant(s)	
	08/935,629		BATES ET AL.	
	Examiner		Art Unit	
	Lyle A Alexander		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2001.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8 and 23-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 23-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other:  |

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In response to the 3/28/01 Appeal Brief, a further search was made, new art was found and the following new rejection will replace the 10/25/00 final rejection.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1, 8, 23-34 and 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dafforn et al. in view of Senior.

Dafforn et al. teach an assay device(10) that contains a test strip(14). There are openings(20,22) for that addition of sample/reagent in the top(36) of device(10). In columns 13-14 lines 67+, Dafforn et al. teach the top(36) can possess an opening or transparent window to view an immunoabsorbing zone and include a scale to quantitate the amount of analyte present in the sample. The sample openings(20,22) have been read on the claimed well/opening and the opening/transparent window on the claimed window. Column 5 teaches a plurality of analytes that include drugs of abuse and HCG. Column 13 teaches a dropper, syringe needle or the like can be use for delivering the sample and that it is advantageous. Finally, Column 13 lines 52+ teaches it is well known, conventional and desirable to attach the top and bottom of the device with a snap fit design having a protrusion on one piece and a receiving means on the other piece.

Dafforn et al. is silent to a snap fit cap/cover means for sealing the top of the sample well/opening and photocopying the results.

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Senior teaches a test device for the detection analytes in urine and a cover for the sample contact area. Senior teaches in column 2 lines 30+ after collection of a sample, the sample collection should be immediately sealed to prevent liquid flow/seep from the test device and contaminate the surroundings. The cover as seen in figure 3 fits over and isolates the sample application portion.

Contamination by biological samples carries the risk of disease and should be avoided. It would have been desirable to avoid any contamination when using the device of Dafforn et al. to avoid the risk of disease. It would have been within the skill of the art to modify Dafforn et al. in view of Senior and incorporate a cap that fits over the sample application openings(20,22) to gain the above advantage of avoiding biological sample contamination. Additionally, Dafforn et al. teaches it is desirable to fit pieces together with a snap fit design. It would have been within the skill of the art to further modify Dafforn et al. in view of Senior and include a snap fit means of securing the cap to prevent it from coming off to gain the above advantages of the snap fit design and minimize biological contamination by securing the cap over the sample.

Photocopying for archiving results or as an easy and inexpensive means of sharing information is notoriously well known in the art. It would have been within the skill of the art to further modify Dafforn et al. and photocopy the results to gain the above advantages.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1,8,23-36,39 and 42-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by WO 97/33519 (WO hereafter).

WO teaches a device for the detection of drugs in body fluids. In figure 1 test card(25) has test strips(26-30) for detection of five different drugs. In figure 11 the card has sample placement areas(51) and result windows(50). In figure 1 the sample area of the card is attached to container(11) which is read on the claimed cap.

Claims 37-38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/33519 (WO hereafter).

See WO supra.

WO is silent to the claimed snap fit engagement of the cap and photocopying the results.

Snap fit engagement is notoriously well known in the art. It is advantageous over screw thread attachment because less dexterity is required to make the attachment. It would have been within the skill of the art to modify WO and use snap fit attachment to gain the above advantages.

Photocopying for archiving results or as an easy and inexpensive means of sharing information is notoriously well known in the art. It would have been within the skill of the art to further WO and photocopy the results to gain the above advantages.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sun teaches a drug detection device but is not available as a reference because of a later filing date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

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June 11, 2001



LYLE A. ALEXANDER  
PRIMARY EXAMINER